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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/698,775

10/31/2003

John J. Allen

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7590

10/13/2006

PHILIP S. JOHNSON
JOHNSON & JOHNSON
ONE JOHNSON & JOHNSON PLAZA
NEW BRUNSWICK, NJ 08933-7003

EXAMINER

NGUYEN, HUONG Q

ART UNIT

PAPER NUMBER

3736

DATE MAILED: 10/13/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/698,775

Applicant(s)

ALLEN, JOHN J.

Examiner

Helen Nguyen

Art Unit

3736

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 31 July 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-6 and 10-13 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-6 and 10-13 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>2/13/2006</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. This Office Action is responsive to the amendment filed 7/31/2006. The amendment to the specification is acknowledged and overcomes the previous objections. Claims 1 and 11 are amended. **Claims 1-6 and 10-13** remain pending.

Information Disclosure Statement

2. The information disclosure statement (IDS) submitted on 2/13/2006 is/are acknowledged. The submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

4. **Claims 1, 2, 5, 10-13** are rejected under 35 U.S.C. 102(e) as being anticipated by Sakata et al (US Pub No. 2004/0215224).

5. In regards to **Claim 1**, Sakata et al disclose a lancing device comprising:
a housing (2) formed with a “cylindrical member” (20) (¶0063);
a lancing mechanism (3) operatively attached to the housing (¶0067);

Art Unit: 3736

a pressure tip, referred to as a “cylindrical member” (8) including an “analysis sensor” (4), moveably attached to the housing for engaging a target site and creating a target site bulge upon being urged toward the target site, wherein Sakata et al disclose pressing said pressure tip against the skin target site, which would contribute to the creation of a target site bulge (§0080, 0081);

a trigger mechanism comprising of a “sensor holder” (7B) and “pivot member” (79) for detecting a target site bulge of a predetermined height created by the urging of the pressure tip against the target site, wherein the urging of the pressure tip against the target site contributes to the creation of said target site bulge, and triggering an immobilization of the pressure tip with respect to the housing. Because the pressure tip is defined with the “analysis sensor” (4) and said sensor becomes immobilized at a predetermined angle, which depends upon the degree of skin bulging, the pressure tip is considered to immobilize as a whole (§0110, 0111). Please see Figure 19 for a detailed drawing.

6. In regards to **Claim 2**, Sakata et al disclose a bias spring (83) for applying a pre-load force against the cylindrical member (8) of the pressure tip (Figure 19), as defined above.

7. In regards to **Claim 5**, Sakata et al disclose a trigger mechanism including at least one locking pawl (7B) and at least one pawl trigger arm (79) wherein the “pivot member” (79) and “sensor holder” (7B), which includes “stopper” (77a), perform a motion-detering function and thus are considered as pawls (§0110).

Art Unit: 3736

8. In regards to **Claim 10**, Sakata et al disclose the trigger mechanism configured to initiate lancing by the lancing mechanism once the pressure tip has been immobilized, as described previously (§0082, 0084).

9. In regards to **Claim 11**, Sakata et al disclose a method for lancing a target site comprising:

providing a lancing device that includes a housing (2, 20), a lancing mechanism (3) operatively attached to the housing, a pressure tip (4, 8 as defined above) moveably attached to the housing for engaging a target site and creating a target site bulge upon being urged toward the target site as explained in the rejection of **Claim 1** above, and a trigger mechanism (7B, 79) for detecting a target site bulge of a predetermined height created by the urging of the pressure tip against the target site as previously detailed and thereafter, triggering an immobilization of the pressure tip with respect to the housing thereby preventing a subsequent change in target site bulge location relative to said housing, also elaborated above in the rejection of **Claim 1**;

contacting the pressure tip with the target site (§0080);

urging the pressure tip towards the target site, thereby creating target site bulge (§0081) that is detected by the trigger mechanism (7B, 79) and triggering an immobilization of the pressure tip with respect to the housing, as described above (§0110, 0111);

lancing the target site bulge with the lancet mechanism (§0082, 0084).

Art Unit: 3736

10. In regards to **Claim 12**, Sakata et al disclose the target site as a dermal tissue target site, skin S (§0080).

11. In regards to **Claim 13**, Sakata et al disclose providing a lancing device that includes a bias spring (83) for applying a pre-load force against the cylindrical member (8) of the pressure tip, as explained previously (Figure 19).

Claim Rejections - 35 USC § 103

12. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

13. **Claims 3,4** are rejected under 35 U.S.C. 103(a) as being unpatentable over Sakata et al in view of Schmelzeisen-Redeker et al (US Pat No. 6589260).

14. Sakata et al disclose a spring (83) to apply a pre-load force against the pressure tip but do not specify the specific strength of the spring. Schmelzeisen-Redeker et al disclose a lancing device with a spring that supplies a force of 10-15 N to optimally control the pressing force needed to operate the lancet (Col.7 line 58-65, Col.8 line 26-30). Therefore, it would have obvious to one of ordinary skill in the art at the time the invention was made to modify the spring disclosed by Sakata et al to provide a force within the ranges of 3-13 N and 9-10 N, as taught by Schmelzeisen-Redeker et al, to provide a sufficient amount of force to operate the lancing device, including that necessary to create a desired target site bulge.

Art Unit: 3736

15. **Claim 6** is rejected under 35 U.S.C. 103(a) as being unpatentable over Sakata et al in view of Shruga (US Pub No. 2005/0038465).

16. Sakata et al disclose a locking pawl (7B) with stopper (77a) but do not disclose the pawl having multiple ratchet teeth. Sakata et al also do not disclose the pressure tip having ratchet teeth, wherein the pressure tip is defined to include "analysis sensor" (4), which is attached to "pivot member" (79), therefore constituting pivot member as a part of the pressure tip (Figure 19). Shruga discloses a lancet device that uses ratchet teeth to engage pawls as an effective method to maintain the depth setting, shown in Figures 47-50 (¶0124 and 0125). Therefore, it would have obvious to one of ordinary skill in the art at the time the invention was made to modify the locking pawl (7B) and the pivot member (79) of the pressure tip, as disclosed by Sakata et al, to both include multiple ratchet teeth as further taught by Shruga, to enhance the immobilization mechanism disclosed by providing a more fitted engagement of the stopper (77a) of the locking pawl (7B) against the pivot member (79) of the pressure tip during immobilization to create a superior trigger mechanism.

Response to Arguments

17. Applicant's arguments filed 7/31/2006 have been fully considered but they are not persuasive. Applicant contends that the pressure tip (4, 8) of Sakata et al does not create the target site bulge upon being urged toward the target site, noting that Sakata et al disclose the use of negative pressure to create said target site bulge. Examiner agrees that Sakata et al disclose using negative pressure to create said target site bulge, however, the

Art Unit: 3736

step of pressing said pressure tip against the skin at the target site (§0080) contributes at least partly to the creation of a target site bulge, and can thus be said to do just that.

18. Applicant also contends that the trigger mechanism (7B, 79) of Sakata et al does not immobilize said pressure tip (4, 8) with respect to the housing (2, 20) such that a change in target site bulge location is prevented relative to said housing due to the existence of springs (74, 83) (Figure 19). However, Examiner notes that Sakata et al disclose that said pressure tip (4) is immobilized at the position where the bulging force of said target site bulge and the spring (74) are in equilibrium (§0082), wherein at said point, the force of spring (74) and therefore spring (83), are balanced by the equivalent and opposing force of said target site bulge and thus cannot be moved further to change the position of said pressure tip or target site bulge with respect to said housing. In fact, Sakata et al disclose that the only way to change the size and thus location of said target site bulge is to change the pressure within said pressure tip (§0092, 0094).

Conclusion

19. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the

Art Unit: 3736

advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Helen Nguyen whose telephone number is 571-272-8340. The examiner can normally be reached on Monday - Friday, 8 am - 5 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on 571-272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

HQN

10/5/2006



MAX F. HINDENBURG
ELECTRONIC PATENT EXAMINER
EBC CENTER 8700